IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of	) Examiner: Prema Maria Mertz
Foo Yew Liew et al.	) Art Unit: 1646
Serial No.: 10/593,247	) Ref No.: 0380-P04195US00
Filed: July 2, 2007	)
For: "Immunosuppressive Cytokine"	)

Petition for Extension Under 37 CFR §1.136(a)

The undersigned hereby petitions for an extension of time of **One (1)** month beyond the time period set in the last office communication. The proper fee under 37 CFR §1.17 is to be charged to Applicant's Deposit Account.

Robert C. Netter, Jr., Ph.D., J.D. — Date: 3/26/08

TRAVERSAL AND REQUEST FOR RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

A restriction requirement under 35 U.S.C. §121 and §372 was set forth in the Official Action dated January 28, 2008 in the above-identified patent application.

At the outset, it is noted that a shortened statutory response period of one (1) month was set forth in the January 28, 2008 Official Action. Therefore, the initial due date for response was February 28, 2008. A petition for a one (1) month extension of the response period is presented with this response, which is being filed within the one month extension period.

It is the Examiner's position that claims 1-12 and 15-31 in the present application are drawn to four (4) patentably distinct inventions which are as follows:

Group I: Claims 1-11, drawn to methods of stimulating proliferation of a regulatory T cell *in vitro* by contacting the cell with EBI3-p35;

Group II: Claims 12 and 15-20, drawn to methods of enhancing regulatory T cell activity in a subject comprising administering EBI3-p35;

Group III: Claims 21-28, drawn to EBI3-p35 molecules; and

Group IV: Claims 29-31, drawn to nucleic acid molecules encoding EBI3-p35.

At page 3 of the instant Official Action, the Examiner has also required the election of a particular species. Specifically, the Examiner has requested that, upon the election of Group 2, a single species of disease must be elected from those recited in claims 17-20. Upon the allowance of a generic claim, additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim will be considered. The Examiner has identified claims 12, 15, and 16 as generic.

The Examiner also notes that, pursuant to MPEP §821.04, when the claims directed to a product are elected and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all of the limitations of the allowable product claim will be rejoined.

Applicants respectfully disagree with the Examiner's restriction of the instant invention and submit that a withdrawal or at the very least a modification of the restriction requirement is clearly in order for the following reasons.

First, it is evident that the Examiner has mischaracterized the instantly claimed invention. Indeed, the Examiner states that claims 1-11 of Group I are drawn to *in vitro* methods of stimulating proliferation of a regulatory T cell. However, claims 1-11 recite no requirement for performing the methods *in vitro*. Claim 1, from which claims 2-11 depend, recites "a method of stimulating proliferation of a regulatory T cell, comprising contacting the cell with EBI3-p35." There is simply no requirement that the regulatory T

cell be contacted with EBI3-p35 *in vitro*. Accordingly, it is without question that claims 1-11 encompass *in vitro* and *in vivo* methods of stimulating proliferation of a regulatory T cell by contacting the cell with EBI3-p35.

Notably, Group II (claims 12 and 15-20) are drawn to methods of enhancing regulatory T cell activity by delivering EBI3-p35 to a subject. Inasmuch as claims 12 and 15-20 and claims 1-11 both encompass *in vivo* methods comprising the contacting of regulatory T cells with EBI3-p35, it is evident there would not be a serious search burden on the Examiner to examine the methods of Groups I and II together. Significantly, the MPEP at §808.01(a) states that a "requirement for restriction is permissible if there is a patentable difference between the species as claimed and there would be a serious burden on the examiner if restriction is not required." Therefore, it is clear that the restriction between Groups I and II should be withdrawn.

Second, Applicants respectfully submit that during the international stage of this application, in the International Search Report and Written Opinion issued June 9, 2005, the PCT Examiner did not make a lack of unity finding and considered all of the claims to be directed to a single invention. Plainly, the instant restriction requirement fails to comply with the established United States Patent and Trademark Office practice of following the international rules regarding unity of invention in the prosecution of applications filed under §371. While the Examiner purports to employ the general inventive concept practice under PCT Rule 13.1, it is wholly unclear how the Examiner could conclude that the instant application has four (4) Groups of inventions and at least eighteen (18) separate species elections, when the PCT Examiner, employing the same rules, determined that the claims in the international application have complete unity of invention. Accordingly, Applicants respectfully request the instant restriction requirement be withdrawn and all of the claims be examined on their merits.

Third, PCT Rule 13.2 sets out that unity of invention is satisfied between groups of claims which share one or more corresponding technical features "that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." Rule 13.2 does not contain any requirement which allows unity to be denied because one group of claims contains features not found in another group. All that is required for claims to be unified is that they share a suitable special technical feature.

Here, Groups I and II at least must be considered unified since both sets of methods explicitly rely on the novel finding that EBI3-p35 is capable of stimulating regulatory T cell proliferation thereby enhancing regulatory T cell activity. Inasmuch as this finding is a clear contribution over the prior art, Groups I and II (claims 1-12 and 15-20) share a special technical feature. Indeed, the Examiner has only stated that "Devergne discloses an EBI3-p35 protein which is a hematopoietic protein." The reference fails to teach that EBI3-p35 is capable of stimulating regulatory T cell proliferation thereby enhancing regulatory T cell activity, as instantly recited in claims 1-12 and 15-20.

For the foregoing reasons, Applicants respectfully request withdrawal or, at the very least, modification of the present restriction requirement to rejoin Groups I and II.

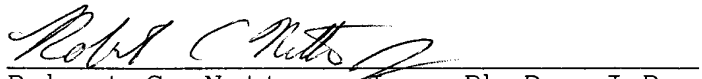
In order to be fully responsive to the instant restriction requirement, Applicants hereby elect, with traverse, Group II, claims 12 and 15-20, drawn to methods of enhancing regulatory T cell activity in a subject comprising administering EBI3-p35. Applicants also elect the species of arthritis as the species of disease. Claims 12 and 15-17 are encompassed by the elected species.

Applicants hereby reserve the right to file one or more continuing applications, as provided in 35 U.S.C. §120, on the subject matter of any claims finally held withdrawn from consideration in this application.

Early and favorable action on the merits of this

application is respectfully solicited.

Respectfully submitted,
DANN DORFMAN HERRELL and SKILLMAN, P.C.

By 
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